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No. 92-1338

In the Supreme Court of the United States

OCTOBER TERM, 1992

DIETARY SUPPLEMENT COALITION, INC., AND THE HEALTH HAUS, INC., PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, a substance is a food additive if its intended use is such that it becomes or may reasonably be expected to become a component of or otherwise affect the characteristics of any food, and if the substance is not generally recognized by scientific experts as safe for such use. 21 U.S.C. 321(s). Classification of substances as food additives is within the primary jurisdiction of the Food and Drug Administration (FDA). The question in this case is whether a coalition of manufacturers and distributors that use a substance as an ingredient in a variety of products may seek a declaratory judgment that the substance is not a food additive even though the FDA has not concluded that the substance is a food additive in the variety of different circumstances in which it is used.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A10) is reported at 978 F.2d 560. The opinion of the district court (Pet. App. A11-A34) is reported at 796 F. Supp. 441.

JURISDICTION

The judgment of the court of appeals was entered on November 5, 1992. The petition for a writ of certiorari was filed on February 3, 1993. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioner Dietary Supplement Coalition (DSC) is a coalition of manufacturers of dietary supplements; petitioner Health Haus is a distributor of dietary supplements. Petitioners manufacture or distribute products containing a substance known as Coenzyme Q10 (CoQ10). Pet. App. A4, A13. In 1989, the government initiated two civil seizure and condemnation proceedings against certain products containing CoQ10 under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 334(a). Pet. App. A4, A13-A14. The proceedings were based on allegations that CoQ10 is an unsafe food additive as used in the seized products, and thus that the seized products are adulterated foods. See 21 U.S.C. 342(a)(2)(C).[1] The FDA also sent "regulatory letters" to DSC members warning them that, as used in their products, CoQ10 is an unsafe food additive. Pet. App. A4, A14.

2. Petitioners filed this action seeking a declaration that CoQ10 is a food rather than a food additive, or alternatively that CoQ10 is generally recognized as safe within the meaning of the FDCA. Pet. App. A4, A12. Respondents moved to dismiss the action, contending that petitioners' complaint failed to present a ripe controversy, and that petitioners had

[1] In one of the seizure actions, the court entered a default judgment of condemnation. See Gov't C.A. Br. 5. In the second action, the district court held that the CoQ10 in the seized products (which included beverages and capsules containing CoQ10 as one of several ingredients) was an unsafe food additive, and condemned the seized articles. *United States* v. *42/30 Tablet Bottles*, 779 F. Supp. 253 (E.D.N.Y. 1991).

failed to exhaust available administrative remedies. Pet. App. A12-A13.

The district court granted respondents' motion to dismiss. Applying the test for ripeness set out in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 148-149 (1967), the district court determined that the questions presented in petitioners' action were not fit for judicial resolution because they required further factual development and had not been finally determined by the FDA. Pet. App. A16-A29. The court further concluded that the hardship to petitioners of withholding judicial review was "to[o] speculative to warrant judicial intervention." Pet. App. A31. The court held that the two seizure actions that occurred in 1989 did not reflect a final determination by the agency that CoQ10 is a food additive. Pet. App. A28. The court also ruled that the threat of future seizures or other enforcement actions posed a hardship no different from that faced by "any company confronted by an interpretation of a law it dislikes." Pet. App. A31, quoting *Estee Lauder, Inc.* v. *FDA*, 727 F. Supp. 1, 5 (D.D.C. 1989).

The district court also concluded that petitioners had failed to exhaust their administrative remedies. The court noted that petitioners had several procedures available to them to obtain a decision from FDA on the status of their products, but "have neither availed themselves of these administrative remedies nor have they alleged, or established, that it would be futile to address their concerns to the FDA." Pet. App. A33.

3. The court of appeals affirmed. Pet. App. A1-A10. First, the court ruled that the FDA's regulatory letters were informal and advisory in nature, and

therefore did not constitute final agency action. Pet. App. A6. Next, the court addressed petitioners' contention that the two seizure actions constituted final agency action on CoQ10. The court noted an apparent "split in authority as to whether seizure actions constitute final agency action," *ibid.*, but went on to explain that in two prior cases in which courts concluded that immediate judicial review was appropriate, the agency had taken some definitive action in addition to the seizure that made explicit its position on the product at issue:

> In *Premo* [*Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795 (2d Cir. 1980)], the agency had considered and refused to approve an application from plaintiff Premo to market the drug at issue. *Premo*, 629 F.2d at 799. In *Natick* [*Paperboard Corp.* v. *Weinberger*, 498 F.2d 125 (1st Cir. 1974)], the agency had already published a regulation banning Natick's food packaging material as violative of the Act.

Pet. App. A7. The court then distinguished this case from *Premo* and *Natick*:

> In the present case, the FDA has made no statement regarding CoQ10 in general; only its use in certain products has been challenged. * * * Even if the FDA has been consistent in its approach to products containing CoQ10, seizures in themselves do not amount to a final agency position on all uses of CoQ10.

Pet. App. A7-A8.

The court of appeals also upheld the district court's rulings that petitioners had suffered no direct and

immediate hardship from the agency's actions, and had failed to exhaust available administrative remedies. Pet. App. A8-A10.

ARGUMENT

In *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 148 (1967), the Court explained that "[t]he injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution." The Court determined that "[t]he problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. In this case, the court of appeals concluded that the issues were not yet ripe for judicial resolution because: (1) they involve "complex chemical and pharmacological considerations" rather than purely legal questions, Pet. App. A7; (2) the FDA has not taken final action on the questions presented, *id.* at A5-A7; and (3) petitioners "failed to show sufficient hardship to require bypassing final agency action by the FDA," *id.* at A9. Those essentially fact-bound determinations warrant no further review.

1. Petitioners contend (Pet. 14-24) that an FDA-initiated seizure action should be deemed to be "final agency action" concerning the classification of a substance within meaning of Section 10 of the Administrative Procedure Act, 5 U.S.C. 704. Petitioners assert that the decision of the court of appeals conflicts with the decisions in *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795

(2d Cir. 1980), and *Natick Paperboard Corp.* v. *Weinberger*, 498 F.2d 125 (1st Cir. 1974), cert. denied, 429 U.S. 819 (1976). Petitioners read too much into *Premo* and *Natick*.[2]

In *Natick*, the FDA had issued a regulation that prohibited residues of polychlorinated biphenyls (PCBs) in excess of ten parts per million in most paper food packaging materials. 498 F.2d at 126. The FDA then announced that it would seek to enforce the new regulation by recommending the seizure of any paper food packaging materials that exceeded the limit established by the regulation. *Ibid.* In this case, in contrast, the FDA has not issued a regulation and has not recommended the seizure of all products containing CoQ10. Indeed, the FDA has not made any "'agency statement' * * * regarding the general use of CoQ10." Pet. App. A7.[3]

In *Premo*, a drug manufacturer had filed an abbreviated new drug application with the FDA. The FDA refused to approve the application as submitted

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[2] In the court of appeals, petitioners also contended that the FDA's regulatory letters constituted final agency action. The court of appeals correctly rejected that contention, see Pet. App. A6 (citing authorities), and petitioners do not press it in this Court.

[3] Petitioners assert (Pet. 11 n.5) that an excerpt from a deposition taken in one of the CoQ10 seizure actions constitutes a definitive statement by the FDA on the classification of CoQ10. The deposition was taken after the district court issued its decision in this case. The court of appeals properly declined to consider the deposition because "it was not before the district court" and "is not a part of the record on appeal." Pet. App. A5. Nor has the FDA conceded that the deposition excerpt is accurate.

and requested additional information. The FDA initiated seizure actions after the manufacturer elected not to provide the requested information, and began marketing the drug without FDA approval. 629 F.2d at 799. The court held that, in those circumstances, the issue "was sufficiently clear to warrant the district court's exercise of its subject matter jurisdiction." *Id.* at 801.

In sum, neither *Premo* nor *Natick* adopted a rule that an FDA-initiated seizure always represents a final agency determination of the classification of a substance under the FDCA. Rather, those decisions simply held that immediate judicial review was appropriate in particular circumstances that included, in addition to the seizures, other agency action that strongly indicated that the agency had reached a final decision on the matters at issue.[4]

2. Even if petitioners were correct in arguing that FDA seizures constitute final agency action reviewable in an action for declaratory relief, petitioners would not be entitled to the relief they seek. Petitioners sought a judicial classification under the FDCA not only of the few products that have been subject to seizure, but also of an undefined variety of other products that contain CoQ10—some as a single ingredient, some as one of several ingredients; some in tablet form, others in capsules, and still others in beverages. Petitioners' request for relief thus went

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[4] The FDA-initiated seizures of products containing CoQ10 were fully subject to judicial review. Consequently, the seizures were not subject to review under the APA. 5 U.S.C. 704 (APA review available where "there is no other adequate remedy in a court").

far beyond the two CoQ10 seizures that occurred in 1989. As the court of appeals explained, "specific product seizures do not amount to final agency action regarding *any* use of CoQ10." Pet. App. A7. Cf. *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 163 (1967) (regulation that constitutes final agency action under 5 U.S.C. 704 is not ripe for judicial review if it ~~merely~~ "serves notice only that the Commissioner *may* under certain circumstances order inspection of certain facilities and data, and that further certification of additives *may* be refused to those who decline to permit a duly authorized inspection").

Petitioners' argument to the contrary rests on a flawed understanding of the analysis that the FDA applies to determine whether a substance is a food additive. Petitioners incorrectly state (Pet. 21 n.7) that it is "immaterial" whether CoQ10 is the single ingredient in a product, or whether it is one of several ingredients. The statutory definition of food additives focuses on whether the substance may "becom[e] a component or otherwise affect[] the characteristics of any food." 21 U.S.C. 321(s). Consequently, as petitioners themselves recognize elsewhere in their petition (Pet. 23-24), the classification decision may turn on whether the substance is a single ingredient or one of several ingredients.

Petitioners also suggest that the particular use to which a product containing CoQ10 is put is irrelevant, asserting that "[i]n fact, the use of all CoQ10 supplements is the same—as nutrients to supplement the daily diet of consumers." Pet. 17. That factual determination should be made by the FDA in the first instance. The FDCA expressly defines a food additive in terms of the intended use of the substance, and also

requires the FDA to determine whether the substance is generally recognized among experts as safe for its intended use. 21 U.S.C. 321(s); see *United States* v. *45/194 Kg. Drums of Pure Vegetable Oil*, 961 F.2d 808, 812-813 (9th Cir.), cert. denied, 113 S. Ct. 375 (1992); *United States* v. *An Article of Food (Coco Rico)*, 752 F.2d 11, 15 (1st Cir. 1985). Because each food additive determination is specific to the particular intended use of a substance in a product, the FDA's treatment of one product containing CoQ10 does not necessarily determine the agency's treatment of other products that contain CoQ10. In deciding whether such products are food additives, the FDA would consider whether there are other ingredients in the product and how the product is used, and then determine whether the CoQ10 can be expected to become a component of or otherwise affect the characteristics of a food, and if so, whether it is generally recognized as safe in that usage.[5] Thus, the FDA's seizure of certain CoQ10 products from two manufacturers says relatively little about how the FDA would treat other products that contain CoQ10 in various configurations with other substances. The courts below were therefore correct in rejecting petitioners' contention that the FDA should be deemed to have made a final determination that CoQ10

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[5] For example, vinegar and baking soda may be safe under a variety of conditions of intended use. But they would not be safe if intended to be mixed together and immediately ingested. See also *United States* v. *Articles of Food* * * * *Buffalo Jerky*, 456 F. Supp. 207, 210-211 (D. Neb. 1978) (sodium nitrate and sodium nitrite, although generally recognized as safe in other products, held to be unsafe food additives when added to buffalo meat).

is an unsafe food additive. Cf. *Lujan* v. *National Wildlife Fed'n*, 497 U.S. 871, 891-894 (1990) (generalized challenge concerning governmental land-use "program" held not ripe for review where alleged "program" consisted only of individualized land-use actions).

3. Petitioners assert (Pet. 25-26) that the court of appeals' decision will permit the FDA "to hold companies' economic fortunes hostage while they pursue enforcement actions immunized from effective legal challenge." That is not so. As the district court explained (Pet. App. A32-A33), petitioners can avail themselves of any of several administrative remedies to obtain a definitive ruling by the FDA concerning the classification of their products under the FDCA. First, petitioners may file a citizen petition seeking a formal agency determination of CoQ10's status as a food or food additive. See 21 C.F.R. 10.25(a). The FDA's decision, which is subject to judicial review, is generally due within 180 days. See 21 C.F.R. 10.30(e)(2), 10.45(d). Second, petitioners may petition the FDA seeking a determination that their uses of CoQ10 are generally recognized as safe. See 21 C.F.R. 170.35, 170.38. Third, petitioners may petition the FDA to issue a regulation prescribing conditions under which CoQ10 may be safely used. See 21 C.F.R. Pt. 171. Fourth, petitioners may seek administrative review of the position expressed in the FDA's regulatory letters. See 21 C.F.R. 10.75.

Petitioners have "neither availed themselves of these administrative remedies nor have they alleged, or established, that it would be futile to address their concerns to the FDA." Pet. App. A33. Instead, petitioners proceeded directly to court seeking a

broad judicial determination that CoQ10 is a food or is generally recognized as safe. Because such a determination implicates complex factual and scientific questions that are within the FDA's area of expertise, both the court of appeals and the district court properly concluded that petitioners should be required to exhaust their administrative remedies. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973); *Biotics Research Corp.* v. *Heckler*, 710 F.2d 1375, 1376-1377 (9th Cir. 1983). [6]

[6] There is no reason to hold this case pending the Court's decision in *Darby* v. *Cisneros*, No. 91-2045 (argued Mar. 22, 1993). The question in that case is whether petitioners were required to exhaust their administrative appeals before seeking judicial review of sanctions recommended by a hearing officer. In this case, petitioners are seeking to go directly to court without obtaining any administrative ruling.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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